

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

S.C. BISTRI-VET SRL
 LIBERTATII STR. 13
 420155 BISTRITA (JUD. BISTRITA-NASAUD)
 ROMANIA

Hoogstraten, 04.02.2020

ORIGINAL
Material

F824050-001079-01 DEXA-KEL 0,2 % 50 ML

Pharmaceutical Form:

Sterile solution

Batch 4006497 / Manufacturing Date 10.2018 Expiry date 10.2022

Inspection lot 40000048482 from 11.2019

CERTIFICATION STATEMENT: I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements

of the Marketing Authorisation of the destination country.

Formula: Dexamethasone sodium phosphate eq. 2 mg dexamethasone -
 Excipient to 1 ml

Aspect: clear, colourless solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (50 ml)	%	100,26	98,00	102,00
Relative density		1,015	1,010	1,050
pH		7,69	6,50	8,50
Refractive index		1,350	1,330	1,370
Id: Dexamethasone Na phosphate		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Dexamethasone na phosph	%	100,85	95,00	105,00
Assay: Na methyl p-hydroxybenz	%	100,71	90,00	110,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 04/02/2020

DEXA-KEL 0,2% 50 ML – batch 4006497 – exp. 10-2022

The undersigned, KELA N.V., confirms that the product DEXA-KEL 0,2% 50 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product DEXA-KEL 0,2% 50 ML has been manufactured according to the formula of DEXA-KEL which has been registered in Romania.

KELA N.V.



kela
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Kela nv

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